

REMARKS

Reconsideration of the application as amended is requested. Applicants affirm the previous verbal election of Group I, claims 7-15 with traverse. The Examiner has not stated any reasons for imposing the Restriction Requirement, as is required by MPEP § 803. Applicants' traverse is maintained on the basis that the Examiner has failed to establish that there is a serious burden if inventions of Group I and Group II are examined together. Withdrawal of the restriction requirement is therefore respectfully requested.

The specification has been amended to clarify the recitation of "ADPG" on page 4, which would have been recognized by those of skill in the art in the context of the paragraph and the application to represent "adenosine diphosphate glucose". *See*, for example, the specification at page 21, line 20 and at page 62, line 26). No new matter has been added by virtue of the amendment to the specification.

Claims 1-6 and 18-20 were previously cancelled. Claim 7 has been cancelled and re-presented as new claim 21. Support for claim 21 appears throughout the application, for example, at page 10, lines 10-14 and as discussed below. Support for the recitation of "construct" in new claim 21 appears at page 12, line 17; page 14, line 1; at page 17, line 18 to page 18, line 27; and at page 21, lines 13-20 of the specification. Support for element a) of new claim 21 appears at page 18, lines 6-7. Support for element b) of new claim 21 appears at page 14, lines 13-16; at page 18, lines 14-19; and at page 62, line 21 to page 63, line 18. Support for element c) of new claim 21 appears at page 10, lines 7-9 and at page 15, line 21 to page 16, line 18; at page 59, lines 21-22 and in Table 8; at page 61, line 6 to page 62, line 16 and in the claims as filed. Support for element d) of new claim 21 appears at page 12, lines 16-19; at page 16, lines 19-20; at page 18, lines 20-25; and in the claims as filed. Support for element e) of new claim 21 appears in the diagram at the top of page 14 and at page 18, lines 25-27. Figures 6, 8B, and 9B show maps of constructs within the scope of new claim 21. Claims 8, 9, and 12 have been cancelled in light of new claim 21. Claims 10, 11, 13, and 14 have been amended to correct the dependency and the antecedent basis. Claims 16 and 17 have been withdrawn by the Examiner. No new matter has been added by virtue of the amendments to the claims.

Objections to the Specification/Claim

The Examiner's attention is directed to pages 2-5 of the Preliminary Amendment filed on July 28, 2003, which amended the specification to address the Examiner's concerns about the sequences appearing on pages 2 and 4, the "SSTS", "TAC", and "CAB" abbreviations, and "one-celled". Repetition of these amendments is not believed to be required. The current amendment to the specification is believed to address the Examiner's remaining objection. Accordingly, withdrawal of all objections to the specification is requested.

The Examiner's objection to claim 7 is believed to be obviated by the re-presentation of claim 7 as new claim 21. Applicants point out that the claim term "hybrid polypeptide" is defined in the specification at page 5, lines 17-25 and that it is settled law that the patentee may be his own lexicographer. *See, Autogiro Co. of America v United States*, 155 USPQ 697, 702 (Ct. Claims 1967).

Withdrawal of the objection to the specification and claim 7 is therefore respectfully requested.

Rejections Pursuant to 35 U.S. C. § 112, Second Paragraph

Claims 7-15 stand rejected under § 112, second paragraph as being indefinite in the recitation of "starch-encapsulating region". The Examiner takes the position that a description and/or corresponding sequence of the region is required. This rejection is respectfully traversed.

The Examiner's attention is directed to page 13, lines 14-18 of the application, where the term "starch-encapsulating region" is defined as follows:

The starch-encapsulating region (SER) is the region of the subject polypeptide that has a binding affinity for starch. Usually the SER is selected from the group consisting of peptides comprising starch-binding regions of starch synthases and branching enzymes of plants, but can include starch binding domains from other sources such as glucoamylase and the like.

Additional defining disclosure occurs in lines 18-27 on page 13, at page 15, lines 21-29, and in Examples One, Six, and Seven. In particular, at page 25 line 25 to page 26, line 7,

Example One teaches how to identify the SER region of any starch synthetic enzyme. Moreover, at page 59, lines 21-22, Example Seven teaches that the SER from the maize soluble starch synthase begins at about amino acid 292.

Furthermore, the concept of starch binding domains of starch synthetic enzymes is well known in the art, as indicated by Chen, et al. (1991) *Biotechnol. Prog.* 7, 225-229 (Reference Q of the IDS submitted on June 14, 2004) and Kusnadi, et al. (1993) *Gene* 127, 193-197 (Reference AK of the IDS submitted on June 14, 2004).

Thus contrary to the Examiner's opinion, those of ordinary skill would readily understand the meaning of "starch encapsulating region" as the term is used the present application. Withdrawal of the rejection of claims 7-15 under § 112, second paragraph is therefore respectfully requested.

Cancellation of claim 12 obviates the rejection of that claim under § 112, second paragraph, and withdrawal of the rejection is respectfully requested.

The amendment to claim 14 is believed to obviate that rejection, and withdrawal of the rejection is respectfully requested.

Rejections Pursuant to 35 U.S.C. § 102

Villand, et al. U.S. Pat. No. 5,977,437

Claims 7, 9, and 13-15 stand rejected under § 102(e) as being anticipated by Villand, et al. The Examiner takes the position that Villand et al. teaches a recombinant polynucleotide comprising a starch branching enzyme and a biologically active polypeptide AGP, and that the rejected claims are anticipated by this teaching. This rejection is respectfully traversed.

At col. 16, lines 43-45, Villand et al. states that the portion of the starch branching enzyme fused to AGP in Example 8 is the "... 75 amino acid potato starch branching enzyme **transit peptide** plus 26 amino acids of the mature branching enzyme." (*emphasis added*). Claim 21, the re-presentation of cancelled claim 7, specifies that a transit peptide (element b) is distinct from the starch encapsulating region (element c) in the claimed construct. Villand et al. contains no teaching or suggestion that the 26 amino acid fragment of the mature branching enzyme present in the AGP fusion enzyme is

capable of binding starch. Furthermore, the Examiner's attention is directed to page 26, lines 2-3 of the application, which states that "[t]he SER region is located nearer to the C-terminus end than the N-terminus end."

Thus the evidence does not support the rejection, and the Examiner has failed to make a *prima facie* case of anticipation of claims 7, 9, and 13-15. *See, In re Oetiker*, 24 USPQ2d 1443, 1444 (Fed.Cir. 1992). Withdrawal of the rejection of those claims over Villand, et al. is therefore respectfully requested.

Block, et al. U.S.Pat.No. 6,307,125

Claims 7-9 and 13-15 stand rejected under § 102(e) as being anticipated by Block et al. The Examiner takes the position that the recombinant polynucleotide set forth in Example 7 of Block et al., which encodes the N-terminus of the α -peptide of beta-galactosidase fused in frame with nucleotides 188-2239 of the wheat soluble starch synthase anticipates claim 7. This rejection is respectfully traversed.

The Examiner's attention is directed to the priority claims of the instant application set forth in the Preliminary Amendment filed on July 28, 2003, page 2. The instant application is a continuation of USSN 09/625,406, filed July 25, 2000, which is a continuation of USSN 08/941,445, filed September 30, 1997 and now U.S.Pat.No. 6,107,060, which claims priority to USSN 60/026,855, which had a filing date of September 30, 1996, The earliest priority claimed by Block et al. is to PCT/EP97/02793, filed May 28, 1997. Applicants believe that since the instant application is examined under the pre-AIPA § 102(e) rules, the earliest effective date of Block et al. under § 102(e) is November 19, 1998, the filing date of USSN 09/196,390, which corresponds to 30 months after the priority date claimed by PCT/EP97/02793. Thus Block et al. is not a proper reference against the instant application under § 102(e), according to MPEP 706.02(f)(1), Example 3. Accordingly, withdrawal of the rejection of the claims under § 102(e) over Block et al. is respectfully requested.

Even if Block et al. were a proper reference under § 102(e), the teaching of Example 7 cited by the Examiner does not anticipate claim 21. The plasmid encoding the fusion protein set forth in Example 7 is suitable only for expression in *E. coli*, and

Example 7 is devoid of any teaching of a promoter adapted to target expression of a payload polypeptide in a starch-containing tissue of a plant during starch formation and a nucleotide sequence encoding a transit peptide. The Examiner's attention is directed to col. 6, lines 27-33 and col. 8, lines 10-15 of Block et al., which teach that deletion of the transit peptide is preferable, and to col. 19, lines 28-30, which discloses that the putative signal peptide of TaSSS is cleaved between amino acids 33 and 34 of SEQ ID NO:1. The Examiner's attention is also directed to col. 21, lines 13-17, in which Block et al. use the terms "signal peptide" and "signal transit peptide" interchangeably. Thus the transit peptide is not present in the pTaSSS Δ 188 plasmid used for *E. coli* complementation studies in Example 7 of Block et al.

Thus the Examiner has failed to make a *prima facie* case that claims 7-9, 13-15 are unpatentable over Block et al. under § 102(e), and withdrawal of the rejection is respectfully requested.

Rejections under 35 U.S.C. § 103

Claims 7 and 9-11 stand rejected under § 103 as being unpatentable over Block et al. The Examiner applies Example 7 of Block et al. to claim 7, and takes the position that it would have been obvious to one of ordinary skill at the time that the invention was made to choose a monocotyledonous or dicotyledonous plant cell for transformation with the claimed polynucleotide in Block. This rejection is respectfully traversed.

As noted above, Block et al. is not a proper § 102(e) reference against the instant application. The plain language of § 103 also eliminates Block et al. as a reference under § 103.

Alternatively, even if Block et al. were a proper § 102(e) reference against the instant application, Block et al. does not teach, suggest, or make the present claims obvious. As noted above, Example 7 of Block et al. discloses no more than an *E.coli complementation assay*. The only teachings of Block relating to plant transformation are in the context of transforming plants only with nucleotides encoding the wheat soluble starch synthase enzyme, or fragments thereof. In fact, as noted above, Block et al.

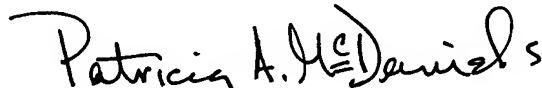
teaches away from transforming plants with nucleotides that include the transit peptide of the wheat soluble starch synthase enzyme.

Withdrawal of the rejection of claims 7 and 9-11 is therefore respectfully requested.

In light of the amendments and arguments presented herein, Applicants submit that all of the rejections contained in the Office Action dated March 28, 2005 have been overcome, and that the application is in condition for allowance. Should the Examiner wish to discuss the application further, he is invited to telephone the undersigned. If any additional fees are due with respect to this submission, authorization is hereby given to charge such fees, or to credit any overpayment, to Deposit Account No. 02-1197.

Respectfully submitted,

BASF CORPORATION

A handwritten signature in cursive script that reads "Patricia A. McDaniels".

Patricia A. McDaniels

Reg. No. 33,194

Customer No. 029137

(919) 547-2834 (direct dial)

(919) 547-2444 (facsimile)

Dated: June 28, 2005